VA WESTERN NEW YORK HEALTHCARE SYSTEM

STANDARD OPERATING PROCEDURES FOR Institutional Animal Care and Use Committee

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Institutional Animal Care and Use Committee

1. PURPOSE

A. To provide guidelines for the Institutional Animal Care and Use Committee (IACUC) at the VA Medical Center as defined in VHA HANDBOOK 1200.7, USE OF ANIMALS IN RESEARCH. The IACUC is a subcommittee of the Research and Development (R&D) Committee.

B. To assure institutional compliance with federal regulations and guidelines and with the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) standards for the care and use of laboratory animals.

C. To provide guidelines for adequate training of all research personnel in the proper handling of research animals, and all research techniques involving animals including, but not limited to, survival surgery.

2. POLICY

A. The IACUC must perform review and oversight functions required by Public Health Service (PHS) Policy, the Animal Welfare Act (AWA), the *Guide for the Care and Use of Laboratory Animals* (the *Guide*), the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) and VA Central Office mandates.

B. The IACUC is responsible for review and oversight of all proposed research and teaching activities utilizing live vertebrate animals when such activities are conducted on VA premises or in affiliated laboratories, and those activities are supported by VA or VA non-profit research foundation administered funds.

C. The IACUC is responsible for review and oversight of training activities of research personnel who conduct research with animals, including research technicians, assistants and associates; students and all others that perform procedures and manipulations in research using vertebrate animals.

D. No experiments involving vertebrate animals may begin (or animals ordered) prior to the following: full written approval of ACORP and all appendices by IACUC; full written approval by R&D Committee, Subcommittee on Research Safety, and the ACOS for R&D; and documentation that the PI and all research staff listed on the ACORP have completed all required animal training.

E. The IACUC has authority to approve or disapprove proposed research activities involving the use of animals. The Institutional Official(s) may not approve activities that the IACUC has disapproved.

F. No member of the IACUC may be excluded from participating in any IACUC activity. All members will be notified in a reasonable amount of time (at least one week whenever possible) of all IACUC activities in order to allow them the opportunity to participate.

G. The IACUC membership must meet the following criteria:

(1) The IACUC will consist of not less than five voting members, and must include at least the following:

(a) One Chairperson

(b) One doctor of veterinary medicine who has training or experience in laboratory animal science and medicine, and who has direct program responsibility for activities involving animals at this VA Medical Center; this member is *ex officio* with vote;

(c) One practicing scientist experienced in research involving animals;

(d) One member whose primary concerns are in a non-scientific area (e.g. ethicist, member of the clergy);

(e) One member who is not affiliated with this VA Medical Center other than as a member of the IACUC and who is not part of the immediate family of a person who is affiliated with the medical center. The person chosen should represent the general community interests in the proper care and treatment of animals.

(f) At least one voting member of the IACUC must be a member of the parent R&D Committee.

(g) An individual who meets the requirements of more than one of the above categories may fulfill more than one requirement; however, the IACUC may not consist of less than five members.

(h) One voting member of the IACUC needs to be a member of the Subcommittee on Research Safety.

(2) IACUC members, in consultation with the R&D Committee, must forward the name(s) of nominees for the IACUC to the Medical Center Director. The Medical Center Director must officially appoint members in writing and specify the length of the appointments.

(3) Members who are not *ex officio* generally serve terms of three years, on staggered appointments. They can be reappointed without a time lapse. The Chair of the committee is appointed annually by the Medical Center Director without a lapse in time and may not simultaneously chair another research committee.

H. Additional IACUC Members may include:

(1) Research Compliance Officer (RCO) is a consultant without vote.

(2) Administrative Officer for Research & Development (AO/R&D) is an *ex officio* member without vote.

(3) Veterinary Medical Unit (VMU) Supervisor is an *ex officio* member with vote.

(4) Associate Chief of Staff for Research & Development (ACOS R&D) is an *ex officio* member without vote.

I. A quorum (defined as a majority, more than 50 percent of voting members) is required in order to convene a meeting of the IACUC, and approval of any aspect of the IACUC responsibility requires a majority vote.

J. Dualities of Interest

(1) The ACOS for R&D and Administrative Officer (AO) for R&D do not serve as voting members on the IACUC, and when in attendance, are attentive to the occurrence or appearance of conflict or duality of interest relative to their supervisory, managerial, or fiscal authority. They will avoid intervention or participation in deliberations involving entities in which they have financial or economic interests, except to provide information as requested by the IACUC.

(2) The VMU Supervisor and Veterinary Medical Officer are attentive to the occurrence or appearance of conflict or duality of interest relative to their supervisory, managerial, or fiscal authority. They will avoid intervention or participation in deliberations involving entities in which they have financial or economic interests, except to provide information as requested by the IACUC.

(3) No IACUC member may participate in the IACUC review, or in the approval of a research project in which the member is personally involved or has a financial conflict in the project, except to provide information requested by the IACUC. The IACUC is responsible for ensuring that the protocol review process is not compromised by conflicts of interest arising from members participating in animal research reviewed by the IACUC.

(4) IACUC members should review and complete the "Research Financial Conflict of Interest Statement" dated May 2011, annually.

3. RESPONSIBILITIES

A. Medical Center Director (Institutional Official (IO))

(1) Ensures that the animal research program has the resources and support necessary to comply with all federal regulations and guidelines that govern animal research.

(2) Appoints IACUC members

(3) Meets with the IACUC Representatives to review and approve the Semi-Annual facility inspection and program review reports

(4) Establishes the institutional climate and provides institutional commitment to humane animal care and use through the IACUC

(5) Reviews and signs annual reports to regulatory and accrediting bodies

B. Chairperson

(1) Has the primary responsibility for presiding over IACUC meetings

(2) Appoints subcommittees of at least two voting members when necessary for special issues, such as compliance or SOP review

(3) Reviews all new protocols, protocol modifications, renewals and personnel changes prior to the meetings.

(4) Works with the Research Compliance Officer to resolve noncompliance issues

(5) Receives requests and reviews justification for designated member review items

(6) Participates in semi-annual facility inspection and program review

(7) Represents the IACUC to VA Central Office, Office of Research Oversight (ORO), Office of Laboratory Animal Welfare (OLAW), AAALAC, and US Department of Agriculture (USDA)

(8) Ensures that IACUC members and all personnel involved in animal research receive and satisfy training and continuing education requirements

C. IACUC

(1) Reviews all new protocols, protocol modifications, renewals and personnel changes prior to the meetings as applicable

(2) Assists in investigating noncompliance issues when needed

(3) Selected members participate in semi-annual facility inspection, file review, and program review

(4) Performs IACUC procedures as listed in Section 4 below (PROCEDURES).

(5) Verifies staff compliance with annual occupational health requirements at the time of annual review of research.

(6) Verify all Principal Investigators and staff listed on the main ACORP have completed the mandatory bi-annual training.

(7) Develops and maintains SOP's per VHA guidelines and local facility requirements.

D. Research Compliance Officer (RCO)

(1) Conducts random inspections and audits of animal use and housing areas, protocols, records and procedures involving animal use, and in house breeding colonies

(2) Submits audit reports to the IACUC committee involving compliance activities for that reporting period

(3) Conducts a file review of 5% or minimum of 5 IACUC records, as part of the semi-annual program review

(4) Conducts routine audits on all protocols approved after January 1, 2008 and "for cause" audits as indicated by oversight committees, senior leadership or other outside agencies.

E. Veterinary Medical Officer

(1) Provides veterinary review of all animal use protocols, renewals, modifications and personnel changes prior to distribution to IACUC members. If the VMO has questions regarding any protocol, the VMO may attempt to resolve any veterinary issues with the principal investigator prior to the IACUC meeting.

(2) Presents reports at IACUC meetings involving animal health issues or issues relevant to the IACUC for that reporting period

(3) Evaluates animals involved in reports of animal welfare concern and/or noncompliance and participates in investigating issues pertaining to animal welfare

(4) Assists in investigating noncompliance issues when requested by the Chair or RCO.

(5) Provides regular training sessions to investigators and research staff that perform procedures or manipulations on laboratory animals. Training topics will include animal usage, federal regulations, and other topics essential for the proper use of animals in research.

F. VMU Supervisor

(1) Ensure quality of animal husbandry

(2) Review and update VMU Program description and IACUC SOPs

(3) Train and manage VMU staff and researchers

(4) Maintain VMU records and inventories

(5) Maintain VMU environmental conditions

(6) Monitor the animal health and welfare

G. IACUC Coordinator

(1) Generates written notification of the results of IACUC reviews including protocol renewal, modification, approval, and miscellaneous letters to the PIs

(2) Generates IACUC agendas and records IACUC minutes

(3) Maintains databases for IACUC Protocols, Personnel, and IACUC Membership Training

(4) Maintains all IACUC records

(5) Distributes information to all IACUC members in regard to meeting dates and other information essential for the activities of the IACUC Committee.

H. Principal Investigator (PI)

(1) Ensures that all protocols, renewals, modifications and other documents that require IACUC review are submitted to the IACUC in a timely manner and contain all information related to proposed animal experiments. The PI is responsible for ensuring the use of current IACUC forms that are available on the research website.

(2) Assures that all active protocols and study procedures involving the use of animals have been reviewed and approved by the IACUC, R&D, and the ACOS for R&D prior to the initiation of research.

(3) Maintains original correspondence from R&D and IACUC committees and keeps records properly stored and secured, and makes them available for review upon request by the RCO or other oversight agencies.

(4) Ensures that all staff involved conduct research in accordance with the approved protocol and follow all policies, SOP's, laws and regulations applicable to the research.

(5) Ensures and provides documentation to the Research Office that all staff, including the PI, have completed all mandatory training such as the web based training "Working with the VA IACUC" and species specific training appropriate for the studies being performed. In addition, the PI is responsible for ensuring that all personnel, including students, are fully trained in all aspects of the animal activities in their lab. This includes, but is not limited to, training in hazardous agent use, Animal User Orientation, Occupational Health & Safety Training, and Medical Center mandatory training.

(6) Promptly reports problems, complications and/or concerns about the use of laboratory animals to the VMU Supervisor, VMO and/or Chairperson.

(7) Corrects deficiencies and infractions in a timely manner and in accordance with the schedule of corrective action as specified by the IACUC.

(8) Maintains all correspondence received from the Research Office for review upon request by the RCO or other oversight agencies.

4. PROCEDURES

A. The IACUC will meet at a minimum biannually and more often as necessary. The committee reviews new protocols, modifications, renewals, and personnel changes of all research proposals when such research includes the use of vertebrate animals.

(1) The Principal Investigator must consult with the Veterinary Consultant during the planning stages of each research study - this should be performed prior to submission to the Research Office. This consult may take the form of a face-to-face meeting or a written review of a draft of the ACORP form. Verification of the discussion should be submitted with the proposal.

(2) The Principal Investigator will request review of the research by submitting a New Protocol Submission Form to the Research Office, with the appropriate number of copies of all supporting documents per the animal protocol submission checklist.

(3) The IACUC Coordinator or Program Assistant checks the investigator education training list to assure that the personnel listed on the main ACORP have completed the mandatory educational training requirements.

(4) The IACUC Coordinator checks the original submission for completeness and accuracy and enters the submission into the database. If any items are missing, the coordinator will notify the Principal Investigator or the designated contact person.

(a) If there are any procedures listed in the protocol that are a departure from PHS policy and the "Guide" they will need to be approved by the IACUC prior to implantation. These departures must also be communicated to the Medical Center Director (Institutional Official) at the time of approval and at continuing review.

B. Initial Proposal Review

(1) All members of the IACUC receive the full proposal in addition to the ACORP and relevant appendices. Comments from the primary scientific reviewer are also provided to the committee. The IACUC may, at its discretion, invite individuals with expertise beyond, or in addition to, that available on the IACUC to assist in the review of research, but they do not vote.

(2) The IACUC minutes record discussion of the research and modifications or other changes to the research required by the IACUC. If the proposal requires modifications, the Chair will assign two voting members to perform the Designated Member Review (DMR) of the requested modifications. Either reviewer may request a full committee review of the modifications.

(3) If the research requires modifications, a notification listing all required modifications and conditions for approval, are sent to the Principal Investigator.

(4) The PI must respond with a letter listing the modifications and all modified signed documents within three (3) months of notification. Failure to do so may result in the need to submit a new proposal.

(5) Once the IACUC Coordinator verifies that the documents contain all the required modifications, they are forwarded to the IACUC Chair and designees to be reviewed and approved. Either of the Designated Reviewers may request a full committee review after reviewing the requested modifications from the Investigator. Approval letters and all applicable forms are signed.

(6) An approval letter from the ACOS of R&D is obtained after all pertinent committees have completed their review and approval.

(6) After all approval signatures are obtained, copies of the approval letters, ACORP and applicable appendices are sent to the Principal Investigator. Following a full review of an Initial Proposal, if the IACUC disapproves the proposal, the Principal Investigator is notified in writing. The Principal Investigator may appeal the decision by submitting a formal written request to the IACUC within 1 month of the notification of disapproval.

(8) All approval letters and the original ACORP and applicable appendices are filed in the Research Office.

(10) The approval date is the date the IACUC Chair signs the approval letter unless there are no modifications required in which case it is the day of the convened meeting.

(11) The IACUC notifies the IO of its decision to approve or withhold approval through copies of the IACUC meeting minutes which are forwarded to the R&D committee upon approval.

C. Initial Designated Member Review (DMR)

(1) If requested by the Primary Investigator, the IACUC Chair will determine if the proposal qualifies for DMR. The ACORP, including any appendices, are submitted to the entire Committee electronically. If full committee review is not called for by any of the voting members of the IACUC within 3 business days, the IACUC Chair will assign a primary and secondary reviewer from the committee voting membership who are not participating in the research. They will receive the application, abstract, main ACORP, including any appendices, and the Research Protocol Safety Survey electronically per the delegated subcommittee reviewer system. They are provided with a primary reviewer form to record their comments. The designated reviewers will determine if the protocol submission is:

- approved as is
- requires modifications, or
- referred to full committee for review

(2) If the research requires modifications, a notification listing all required modifications and conditions for approval are sent to the Principal Investigator.

(3) The PI responds to the Designed Member Reviewers with a letter containing a complete listing of the modifications made and all modified signed documents (within 3 months of the notification.)

(4) Once the IACUC Coordinator verifies that the documents contain all the required modifications, they are forwarded to the Designated Member Reviewers to be reviewed and approved. Approval letters and all applicable forms are signed.

(5) Once the IACUC Coordinator verifies that the primary reviewers are satisfied with the required modifications, the IACUC Chair signs the Designated Member Review approval letter and applicable forms.

(6) An approval letter from the ACOS of R&D is obtained after all pertinent committees have completed their review and approval.

(7) After all approval signatures are obtained, the approval letters and copies of the ACORP and applicable appendices are sent to the Principal Investigator.

(8) All approval letters and the original ACORP and applicable appendices are filed in the Research Office.

(9) The IACUC is notified of the approval of the research in the agenda of the next scheduled IACUC meeting.

(10) The IACUC notifies the IO of its decision to approve through copies of the IACUC meeting minutes which are forwarded to the R&D committee upon approval.

D. Annual Review of Animal Research

(1) Approximately 2 months before the date of the IACUC meeting, at which annual review is scheduled, the IACUC Coordinator sends a Continuing Review Submission Form to the Principal Investigator including a request for a review of the currently approved Research Protocol Safety Survey. Also requested to be included with the submission is the original abstract and an updated progress report including a literature review.

(2) Upon receipt of the completed signed continuing review form and applicable attachments from the Principal Investigator, the IACUC Coordinator stamps it with the date of receipt and places it on the IACUC agenda for review and approval.

(3) If, after review by the full committee, the proposal requires modifications, the Chair will assign two voting members to perform the Designated Member Review (DMR) of the requested modifications. Either reviewer may request a full committee review of the modifications.

(4) Once the IACUC Coordinator verifies that the primary reviewers are satisfied with the required modifications, the IACUC Chair signs the approval letter and applicable forms.

(5) An approval letter from the ACOS of R&D is obtained after all pertinent committees have completed their review and approval.

(6) Approval letters and the original Continuing Review Submission form are filed in the Research Office.

(7) Approval letters and copies of the Continuing Review Submission form are sent to the Principal Investigator.

(8) The IACUC is notified of the approval of the research in the agenda of the next scheduled IACUC meeting.

(9) The IACUC notifies the IO of its decision to approve through copies of the IACUC meeting minutes which are forwarded to the R&D committee upon approval.

E. Three Year ACORP Renewal

(1) Approximately 2 months before the date of the IACUC meeting, at which the three year review is scheduled, the IACUC Coordinator sends the Principal Investigator the 3 year renewal Submission form. This requires the submission of a complete new ACORP, abstract and Research Protocol Safety Survey (RPSS).

(2) The signed documents will be reviewed and processed as described above for a initial submission (Section D-3, above).

F. Amendments: Full Review

(1) Principal Investigators may request an amendment to an approved animal research proposal by submitting a Protocol Amendment Form which may require a revised ACORP or Appendix plus a copy of all revised documents.

(2) The signed documents will be reviewed and processed as described above for an annual review submission (Section D-3-9, above)

(3) Major changes to the research include, but are not limited to, changing animal species, changing age or sex of animals, adding a surgical component, or change in principal investigator. All major revisions must go through a full review process as described above under "Procedures, Section C. Initial Proposal Review.

*Removal of staff is a minor change that only requires a notification to the IACUC in the agenda of the next scheduled IACUC meeting.

G. Amendment: Designated Member Review

Revisions that represent a **minor change** may be reviewed and approved by the Designated Member Review Process if requested by the Principal Investigator.

(1) The IACUC Chair reviews the request to determine if the requested changes are minor and qualify to be reviewed by the DMR process.

(2) The amendment and all associated documents are submitted to the entire Committee electronically. If full committee review is not called for by any of the voting members of the IACUC within 3 business days, the IACUC Chair will assign a primary and secondary reviewer from the voting committee membership who are not participating in the research. The Designated Reviewers may approve, request modifications or request a full committee review of the amendment.

(3) After all approval signatures are obtained, the original approval letter and copies of the ACORP and applicable appendices are sent to the Principal Investigator.

(4) Upon approval the signed documents will be reviewed and processed as described above for an annual review submission Section D-3-9, above)

H. Transfer of animal number limits from one year to next year

(1) Principal Investigators may request a transfer of animal number limits from one year to the next year by submitting a formal written request with the continuing review submission form or as an amendment.

I. Facility Inspection and Review of Animal Care and Use Program

(1) At least once every six months, the IACUC will inspect all facilities, including animal housing and study areas and review the institution's program for humane care and use of animals, using the Animal Welfare Act and the Guide as a basis for evaluation, and the “VA SEMIANNUAL EVALUATION of the INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES, Part 1 – Checklist Section A. Review of the Program and Section B. Inspection of the Facilities”. ".

(2) The IACUC Chair will conduct a review of the animal research facility with at least three voting committee members prior to the next scheduled meeting.

(3) The semi-annual program and facility reviews will be discussed at the next scheduled IACUC meeting.

(4) Entries on "VA SEMIANNUAL EVALUATION of the INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES PART 2 -- Table of Deficiencies and Departures", will be drafted at the IACUC meeting. The report distinguishes significant deficiencies from minor deficiencies. The IACUC recommends appropriate corrective action to resolve issues identified during the walk-thru and a timeline for their completion. The facility inspection report remains an open IACUC agenda item until all corrective actions have been completed to the satisfaction of the IACUC. A majority of all voting IACUC members at this meeting must approve the report.

(5) , **"**VA SEMIANNUAL EVALUATION of the INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES PART 3 – Post-Review Documentation" will be completed and signed by all appropriate individuals, including a majority of all voting IACUC members. The IACUC Representatives will schedule a meeting with the Medical Center Director to review the document and obtain his signature.

(6) A signed, unaltered copy of the complete report (including Parts 1 A & B, 2 and 3) must be sent through the ACOS R&D and Medical Center Director to the CVMO within 60 days of the self-assessment date. The IACUC semi-annual report may not be altered by any local official under any circumstance once the IACUC has voted to approve the report.

(7) A copy of the report should be submitted to the R&D Committee for review. R&D approval is not required before submission of the final document to the CVMO.

(7) The original signed complete report must be retained for at least 3 years.

(8) The IACUC maintains minutes of its meetings and they shall be written and published within three (3) weeks of the meeting date. Minutes are submitted to the R&D Committee for review and consideration, which may accept or reject its recommendations, but may not alter an adverse report or recommendation (for example, reverse an IACUC action resulting in disapproval based on ethical or legal reasons). The recommendations of the IACUC are then forwarded to the Medical Center Director (MCD) through the R&D Committee. The MCD is an ex-officio member of the R&D Committee which receives all program related issues the IACUC deem appropriate and meets with members of the IACUC semi annually to review the program review. In addition, the ACOS, the IACUC Chair and the VMO contact the MCD for any program or facility related concerns as applicable.

J. Closure of research

Prior to the closure of any study, the principle investigator must submit the IACUC Protocol Closure Form as notification of his/her intention to close the study. This form must be submitted in a timely manner so that proper action can be taken before the official close of the study. The IACUC coordinator will provide notification to the IACUC and R&D committees of the study closure.

K. Record Keeping

(1) Minutes of IACUC meetings are kept in the Research Office for a minimum of 3 years.

(2) All records of IACUC correspondence are maintained in the applicable research file for each study.

(3) This institution will maintain records that relate directly to applications, proposals, and proposed changes for ongoing activities reviewed and approved by the IACUC for the duration of the activity and per the record control schedule

(4) All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

L. Noncompliance and Suspension of Activities

(1) Noncompliance is defined as, but not limited to, any of the following:

(a) Activity of animal use prior to written IACUC, Biosafety, and R&D approval.

(b) Proceeding with changes in activities without written IACUC approval or failure to adhere to the activities as described in an approved protocol ("protocol violation").

(c) Research activity involving animals that is not associated with an approved and current ACORP.

(d) Any violation of the animal care and use provisions of the Animal Welfare Act, the PHS Policy on Humane Care and Use of Laboratory Animals, the NIH Guide for the Care and Use of Laboratory Animals, or any applicable VA policies or SOP's.

(e) Procedures conducted past the approval period or by unauthorized or untrained personnel.

(2) The RCO and the IACUC Chair will promptly review possible incidents of noncompliance in accordance with all appropriate regulations and guidelines, and will attempt to determine whether the alleged noncompliance incident represents a major or minor infraction. The IACUC may suspend activity that has previously been approved after a full review of the matter at a properly convened meeting. The vote to suspend must be made by a majority of the members at the meeting. However, the Medical Center Director has given the authority to the VMU Supervisor, Veterinary Medical Consultant or the IACUC Chair to temporarily halt any activity which they deem to be inhumane, improper, or hazardous to either animals or personnel. The IACUC will review the incident at the next fully convened meeting. If necessary, the IACUC will call an emergency meeting. In accordance with VHA Handbook 1058.01, should the IACUC determine that a reportable incident or event occurred, the IACUC Chair or designee must report the determination directly (without intermediaries) to the Medical Center Director within 5 business days after the IACUC's determination. The report must be in writing, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research review committee. The following restrictions will be immediately imposed: no additional animals may be entered into the study, no animals should be removed from the study if doing so could potentially result in pain distress or injury and no animal should be removed from the study if doing so could potentially impact or invalidate the data already obtained.

The Medical Center Director must report the IACUC's determination (i.e. that a reportable

incident or event occurred) to ORO CO with a simultaneous copy to the VISN Director and the ORD within 5 business days after receiving such notification. An initial report of an IACUC determination is required regardless of whether the determination is preliminary and still under investigation or final disposition of the matter has been resolved at the time of the report.

(3) Upon notification of an allegation of non-compliance (major or minor), all research activity which has been determined to be in non-compliance will immediately cease until the situation is resolved to the satisfaction of the VMU Supervisor, RCO, IACUC Chair, and Veterinarian. The ACOS, IACUC Chair, and the Veterinarian have the authority to temporarily halt the activities of any research which in their opinion is in non-compliance and / or places animals at risk of pain or suffering. Based on report of the person(s) making the report of non-compliance, the IACUC Chair will contact the PI in writing listing the infractions in detail. The PI must respond within 10 business days to the itemized infractions and provide a written corrective action plan with a timetable, if appropriate. Research may continue only when the PI receives in writing that all non-compliance issues have been resolved in a satisfactory manner.

(4) A written report of an investigation is submitted to the full committee for review and approval. If necessary, a special meeting of the IACUC will be convened to review the allegations. If the results of the investigation require an action plan, one is developed by the IACUC Chair and the Veterinary Medical Consultant and noted in the report. The report is signed by a majority of the members present at a convened IACUC meeting and sent through the ACOS/R&D to the Research and Development Committee for submission to the Medical Center Director within five (5) business days of the allegation. If the action plan includes suspension of the study, the IO in conjunction with the IACUC will review the reason for suspension, take appropriate corrective action and report that action with a full explanation to the Chief Veterinary Medical Officer, the Regional Office of Research Oversight, OLAW and AAALAC through the ACOS/R&D and the Medical Center Director. A copy of the report is also forwarded to the Chief Veterinary Medical Officer, VA Headquarters through the ACOS/R&D within thirty (30) days of the allegation.

(5) The IACUC coordinator will maintain complete documentation of noncompliance incidents and all notifications to PI's and their responses in the study file.

M. Reporting Animal Concerns and Whistleblower Policy

(1) The Research Service is committed to the humane care and use of laboratory animals. To ensure that laboratory animals receive humane care and use or treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research, the IACUC must review and if warranted, address any animal-related concerns by the public or by Medical Center employees. The IACUC must review each concern in a timely and systematic manner and when necessary take prompt and appropriate corrective action.

(2) Reports of animal welfare concerns may be made anonymously, if desired. However, if the complainant would like to know the resolution of the investigation, he or she must provide a name. All reports will be handled confidentially, although anonymity cannot be guaranteed.

(3) Any concerns or deficiencies in the care and/or treatment of animals or any activities related to animal care that may be improper or inhumane, may be reported. Concerns may be reported to one's direct supervisor, the Attending Veterinarian, the Chief of Research

the IACUC Chair or the VMU Supervisor. Reporting may be done verbally, in writing or by e-mail. When reporting, as much factual information as possible should be included.

(4) Protection from retaliation is a very important issue. If one believes that they have been retaliated against for whistle blowing, a formal complaint can be filed with the Human Resources Department of the Medical Center.

(5) There are numerous signs throughout the VMU stating our Whistle Blowing Policy and the steps for reporting concerns.

P. Reports to outside agencies and headquarters

(1) Applicable annual reports are sent to the USDA, VA Headquarters, OLAW and AAALAC, International in a timely manner per VHA 1200.7 and will contain all required information.

(2) Findings of noncompliance will be reported to the appropriate agencies in a timely manner, as required by the relevant agency and/or VHA Handbook1058.01.

(3) Any change in the accreditation status of the Institution (e.g. if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.

(4) The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

(a) Any serious or continuing noncompliance with the PHS Policy

(b) Any serious deviations from the provisions of the "Guide"

(c) Any suspension of an activity by the IACUC

Q. Post-Approval Monitoring

(1) The IACUC has the responsibility to monitor experimental animal procedures, particularly when there is a potential for producing pain or distress to animal subjects. This responsibility can be met in three ways:

(a) Performance of random protocol audits and unannounced inspections of laboratories and/or areas where animals are used or housed.

(b) When requested by the IACUC, the VMU Staff will observe specific procedures and/or observe animals post-procedure and report to the IACUC an evaluation of training competency and or pain/distress level of the animals.

(c) The IACUC provides continuing review of all animal use protocols at least once annually.

R. Sentinel Animals and Educational Use of Animals Review

(1) Sentinel animals are used to monitor and determine the overall health of the general animal population, not for experimentation.

(2) Proposed use of animals for instructional or educational purposes must be reviewed and monitored by the IACUC following the same process as that employed for research proposals.

S. Review of Hazardous Material to be used in Animal Research

(1) Each lab must follow applicable Medical Center safety guidelines.

(2) The research approval process requires that the PI provide a chemical inventory, and a list of all recognized chemical, biological and radiological hazards. The Subcommittee on Research Safety scrutinizes the proposed use of chemicals, biohazard substances or radioisotopes. Research cannot go forward if the appropriate committees have not approved their use, or if personnel are not properly trained, or if the PI is not permitted to possess the substances according to federal or VA regulations. This subcommittee, which includes a Biosafety Officer, Radiation Safety Officer and biological safety expertise from the VA staff and the academic affiliate, reviews each research protocol, and the attached list of materials to be used.

T. IACUC Member Training

(1) New IACUC members receive orientation by the IACUC Chair in areas of protocol review, inspection procedures, IACUC responsibilities and reporting requirements.

(2) All IACUC members must complete the VA version of the web based training course and exam entitled “Essentials for IACUC Members”.

(3) All IACUC members will receive continuing education in relevant animal use/care topics at least four times per year during the IACUC meeting. The content of the education is determined by the IACUC Chair, VMU Supervisor or VMO.

(4) Additional Training opportunities may include:

(a) One-on-one training with the Chair, VMO, VMU Supervisor, RCO or other qualified IACUC member.

(b) Individually reviewing federal, state, local or institutional laws, regulations, policies or SOP’s.

(c) Completion of web-based training courses or compact discs available from VA Office of Research and Development, the OLAW (PHS Policy on Humane Care and Use of Laboratory Animals tutorial), the Animal Welfare Information Center Workshop and others.

(d) Participate in ARENA/PRIM&R IACUC 101 and 201 courses.

(e) Educational seminars provided by the VMO.

U. Investigator, research staff, and VMU staff training

(1) Before an animal protocol can be activated, all staff listed on each protocol must have been adequately trained (see: USDA A WAR, 9 C.F.R. §2.32(a); Principle 8, U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, And Training). At a minimum, the training utilized will cover all topics listed in USDA AWAR, §2.32(c).

(2) The Office of Research and Development (ORD) has developed free web-based training that helps meet mandatory training requirements for research staff. ORD web-based training may be utilized on an annual basis to demonstrate compliance with Federal animal research training mandates, unless alternate and equivalent annual training approved by the CVMO has been adopted. Education goals for web-based training will be considered met when personnel are able to pass an exam that covers important topics in the training. The exam must be of sufficient difficulty to provide some assurance that important concepts have been learned.

(a) Investigators and research staff who utilize laboratory animals and are listed on the ACORP must pass the exam "Working with the VA IACUC" web course, in addition to any species-specific course that covers the species proposed for use (can be found at: www.citiprogram.org/default.asp.)

(b) Individuals wishing to utilize alternate web-based, didactic, or other types of training in place of ORD web-based training must document in writing to the CVMO that the alternate training covers all areas required by USDA Animal Welfare Act Regulations on an annual basis. If documentation is not deemed adequate, ORD web-based training, or more stringent alternative training must be adopted as approved by the CVMO.

V. VA and Affiliate IACUCs.

(1) When a VA investigator is performing animal research within non-VA laboratories that has been approved by an AAALAC-accredited affiliate institution's IACUC with whom there is a memorandum of understanding concerning reciprocity, the VA IACUC will not supersede any adverse action taken by the affiliate IACUC against such a study. The VA IACUC will not allow work on the study to continue when approval by the affiliate IACUC lapses or is suspended.

(2) When a VA investigator is performing animal research within VA laboratories, and that research has also been approved by an affiliate institution's IACUC, the affiliate IACUC will not supersede any adverse action taken by the VA IACUC against such a study. The VA IACUC will not allow work on the study to continue when VA approval lapses or is suspended.

(3) If a VA investigator is performing animal research within non-VA laboratories on a project that has also been approved by both an affiliate institution's IACUC and the VA IACUC, the research will not be able to be performed if either the affiliate IACUC or the VA IACUC approval lapses or is suspended.

(4) If the VA IACUC and the affiliate IACUC have an agreement for partial or full-protocol reciprocity, complete records must be kept at the VA for protocols reviewed under such agreements.

(5) The minutes of joint or affiliate IACUCs concerning VA relevant protocols need to contain the same format and information indicated for VA studies, and will be included in the VA IACUC minutes

5. REFERENCES

A. Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, 2011

B. Public Health Service Policy on Humane Care and Use of Laboratory Animals, U.S. Department of Human Resources, Public Health Service, NIH. Revised 2002

C. Animal Welfare Act (PL 89-544) and all subsequent amendments

D. VHA Handbook 1200.7 “Use of Animals in Research”. November 23, 2011.

E. USDA A WAR, 9 C.F.R. §2.32(a); Principle 8, U.S. Government Principles For The Utilization And Care Of Vertebrate Animals Used In Testing, Research, And Training

F. VHA Handbook 1200.58 “Research Compliance Reporting Requirements”. November 15, 2011

6. FOLLOW-UP RESPONSIBILITY

IACUC Chairperson

7. RESCISSION

None

8. AUTOMATIC REVIEW DATE

August 2013

Distribution: All Principal Investigators Using Animals